(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 317 227 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
17.11.2004 Bulletin 2004/47

(21) Application number: **01968890.2**

(22) Date of filing: **13.09.2001**

(51) Int Cl.[7]: **A61F 2/00**

(86) International application number:
PCT/US2001/028869

(87) International publication number:
WO 2002/022047 (21.03.2002 Gazette 2002/12)

(54) IMPLANTABLE PROSTHESIS

IMPLANTIERBARE PROTHESE

PROTHESE IMPLANTABLE

(84) Designated Contracting States:
DE ES FR GB IT

(30) Priority: **14.09.2000 US 661623**

(43) Date of publication of application:
11.06.2003 Bulletin 2003/24

(60) Divisional application:
04020837.3

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Description

[0001] The present invention relates to an implantable prosthesis and, more particularly, to a composite prosthesis for use in soft tissue repair and reconstruction that limits the incidence of postoperative adhesions.

Discussion of Related Art

[0002] Various prosthetic materials have been proposed to repair and reinforce anatomical defects, such as tissue and muscle wall hernias. For example, ventral and inguinal hernias are commonly repaired using a sheet of biocompatible fabric, such as a knitted polypropylene mesh (BARD MESH). The fabric is typically sutured, stapled or otherwise provisionally anchored in place over, under or within the defect. Tissue integration with the fabric, such as by tissue ingrowth into and/or along the fabric, eventually completes the repair.

[0003] It has been suggested that in certain procedures, the prosthetic fabric may come into contact with tissue or organs potentially leading to undesirable postoperative adhesions between the mesh and the tissue or organs. It had been proposed in U.S. Patent No. 5,593,441, assigned to C.R. Bard, Inc., also the assignee of the present application, to repair ventral hernias and/or reconstruct chest walls using a prosthesis that is covered with an adhesion resistant barrier, such as a sheet of expanded PTFE. In the repair of ventral hernias, the composite is positioned with the barrier facing the region of potential adhesion, such as the abdominal viscera, and in the case of chest wall reconstruction, the barrier faces the thoracic viscera (i.e., heart and lungs). Other configurations of composite prostheses can be found in U.S. Patent Nos. 5,695,525; 5,725,577 and 5,743,917, each of which is also assigned to C.R Bard, Inc.

[0004] International Publication No. WO 97/35533, also assigned to C.R. Bard, Inc., proposed a universal composite prosthesis in which one side of a layer of mesh material is covered with a layer of barrier material. The mesh material promotes biological tissue ingrowth while the barrier material retards biological tissue adherence thereto. The prosthesis may be utilized for various surgical procedures, including ventral hernia repair and inguinal hernia repair.

[0005] It is an object of the present invention to provide an improved prosthesis for the repair of tissue and muscle wall defects.

[0006] The present invention is an implantable prosthesis according to claim 1. Embodiments of the invention are referred to in the dependent claims.

[0007] Other objects and features of the present invention will become apparent from the following detailed description when taken in connection with the accompanying drawings. It is to be understood that the drawings are designed for the purpose of illustration only and are not intended as a definition of the limits of the invention.

[0008] The foregoing and other objects and advantages of the invention will be appreciated more fully from the following drawings, wherein like reference characters designate like features, in which:

FIG. 1 is a top plan view of an implantable prosthesis in accordance with one illustrative embodiment of the present invention;
FIG. 2 is a bottom plan view of the prosthesis of FIG. 1;
FIG. 3 is a cross-sectional view of the outer margin of the prosthesis taken along section line 3-3 of FIG. 1;
FIG. 4 is a top plan view of an implantable prosthesis in accordance with another illustrative embodiment of the present invention;
FIG. 5 is a bottom plan view of the prosthesis of FIG. 4;
FIG. 6 is a cross-sectional view of the outer margin of the prosthesis taken along section line 6-6 of FIG. 4;
FIG. 7 is a fragmented view of the outer margin of the prosthesis of FIG. 5;
FIG. 8 is a cross-sectional view of the outer margin of a prosthesis in accordance with another illustrative embodiment of the present invention;
FIG. 9 is a cross-sectional view of the outer margin of a prosthesis in accordance with a further illustrative embodiment of the present invention; and
FIG. 10 is a cross-sectional view of the outer margin of a prosthesis in accordance with still another illustrative embodiment of the present invention.

[0009] FIGS. 1-3 illustrate one embodiment of an implantable prosthesis for repairing soft tissue and wall defects, such as ventral and inguinal hernias, and/or for chest wall reconstruction by promoting tissue ingrowth thereto while limiting the incidence of postoperative adhesions to selected portions of the prosthesis. The prosthesis 20 includes a layer of tissue infiltratable repair fabric 22, an adhesion resistant barrier layer 24 overlying at least a portion of one side of the fabric, and a peripheral barrier 26 extending about a portion of the outer peripheral edge 28 of the fabric.

[0010] The repair fabric 22 is formed of a biologically compatible, flexible material that includes a plurality of interstices or openings which allow sufficient tissue ingrowth to secure the prosthesis to host tissue after implantation. The barrier layer 24 and the peripheral barrier 26 are formed of a material and/or with a structure that does not substantially stimulate tissue ingrowth and adhesion formation when implanted in tissue to limit the incidence of postoperative tissue adhesions between the fabric and adjacent tissue and organs.

[0011] The prosthesis 20 may be relatively flat and sufficiently pliable to allow a surgeon to manipulate the shape of the implant to conform to the anatomical site

of interest and to be sutured or stapled thereto. The shape and size of the composite implant, and of the respective repair fabric 22, barrier layer 24 and peripheral barrier 26, may vary according to the surgical application as would be apparent to one of skill in the art. In this regard, it is contemplated that the prosthesis may be preshaped or shaped by the surgeon during the surgical procedure. It is also contemplated that two or more sheets of fabric and/or barrier material may be implemented in one or more layers of the prosthesis. The layers may have the same size and shape, or may have a different size and/or shape. A separate layer of material may be employed between the repair fabric and the barrier layer. The prosthesis also may have a plug or three-dimensional shape, with selected portions, or all of, the edges of the plug covered by barrier material.

[0012] As illustrated, the barrier layer 24 may cover the entire surface of a first side 30 of the repair fabric 22. This particular configuration allows tissue ingrowth to a second side 32 of the repair fabric while inhibiting adhesions to tissue and organs located opposite the anatomical defect site. It is to be appreciated, however, that the barrier layer 24 may be configured to cover only selected portions of the first side of the fabric 22 to enhance tissue ingrowth from both sides of the fabric in those portions free of the barrier layer.

[0013] In some instances, it may be desirable to isolate the outer peripheral edge of the repair fabric from adjacent tissue and organs. In the illustrative embodiment, the peripheral barrier 26 extends completely about the outer peripheral edge 28 of the fabric to inhibit adhesions thereto. It is to be understood, however, that the peripheral barrier 26 may be configured to cover only selected portions of the outer peripheral edge of the fabric that one may wish to protect from the formation of postoperative adhesions, such as portions of the edge that may be exposed to tissue and organs.

[0014] The peripheral barrier 26 may be formed integral with either the repair fabric 22 or the barrier layer 24. Alternatively, the peripheral barrier 26 may be formed by a separate component that is attached to or incorporated into the outer peripheral edge of the implant.

[0015] In one illustrative embodiment shown in FIGS. 1-3, the peripheral barrier 26 is formed from a portion of the repair fabric 22. In particular, the repair fabric 22 may be altered so as to substantially eliminate the tissue infiltratable interstices or openings along its outer margin, thereby creating a peripheral barrier 26 which inhibits tissue ingrowth to the outer peripheral edge 28 of the fabric.

[0016] In one embodiment, the outer margin of the repair fabric 22 is melted to seal the fabric material and form an outer peripheral barrier 26. The barrier layer 24 may be configured, such as with submicronal sized pores, so that a portion of the melted fabric material becomes fused to the barrier layer 24. In this arrangement, the peripheral barrier 26 may act to increase the stiffness of the outer margin of the barrier layer, such that the outer edge of the barrier layer may become more resistant to being inadvertently folded back. Additionally, the outer margin of the barrier layer may tend to soften and thereby reduce the brittleness of the peripheral barrier. The outer peripheral barrier may have a width that is approximately equal to or greater than the thickness of the fabric material.

[0017] The outer margin of the fabric 22 may be melted using any suitable process as would be apparent to one of skill in the art. In one embodiment, the outer margin may be melted by heat sealing the fabric. Other processes may include ultrasonic, induction, vibration, infrared/laser welding and the like.

[0018] As shown in FIG. 3, the peripheral barrier 26 may be configured to decrease in thickness in an outward direction away from the outer peripheral edge 28 of the repair fabric and toward the outer edge of the barrier layer 24. In one embodiment, the peripheral barrier 26 has a tapered shape resulting in a low profile edge relative to the rest of the prosthesis that may enhance the adhesion resistance of the peripheral barrier 26. The tapered shape may also provide the prosthesis with a relatively flexible, adhesion resistant outer margin. It is to be understood, however, that any suitable shape may be employed for the peripheral barrier as would be recognized by one of skill in the art. For example, the peripheral barrier 26 may be formed with a stepped configuration, with a non-uniform taper, or with a constant thickness.

[0019] In another illustrative embodiment shown in FIGS. 4-6, the peripheral barrier 26 is formed from a portion of the barrier layer 24. In particular, the outer margin of the barrier layer may be extended along a portion of the layer of repair fabric 22 so that it covers at least a portion of the outer peripheral edge 28 of the fabric.

[0020] In one embodiment, the outer margin of the barrier layer 24 is wrapped about the repair fabric 22 so that it extends from the first side 30 of the repair fabric and across the thickness of the outer peripheral edge 28 of the fabric. The barrier layer 24 may further extend inwardly across a portion of the second side 32 of the fabric adjacent the outer peripheral edge 28. The barrier material may be hemmed about the repair fabric and secured with stitches 34, 36 placed inward of the outer peripheral edge of the fabric. This configuration essentially encapsulates the outer peripheral edge of the fabric with barrier material to inhibit adhesions thereto.

[0021] The barrier material, however, does not need to wrap around the peripheral edge and across the second side of the fabric as shown in FIG. 6. In this regard, the barrier material may extend across and be joined to the outer peripheral edge of the fabric. For example, the barrier material may be bonded to the outer peripheral edge of the fabric with any suitable adhesive, such as a silicone, that is compatible with the particular fabric and barrier materials.

[0022] It may be desirable to configure the hemmed

portion of the prosthesis with fluid drainage so as to reduce the potential for entrapping fluid along its outer margin that could lead to a seroma and/or an infection. In one illustrative embodiment shown in FIGS. 5 and 7, the portion of the barrier layer 24 overlying the second side 32 of the repair fabric 22 includes a plurality of apertures 38 adjacent the outer peripheral edge 28 of the fabric. The apertures 38 should have a sufficient size and be located to permit fluid drainage. In this regard, the apertures 38 may be spaced inwardly and slightly away from the outer peripheral edge 28 of the fabric, as shown in the figures.

[0023] In one embodiment, the apertures 38 may include slits that extend inwardly away from the peripheral edge 28 of the fabric. As shown, the slits may have a generally V-shape that not only allows fluid drainage, but also reduces the likelihood of developing wrinkles or puckers along the outer margin of the prosthesis as the barrier layer is wrapped about the peripheral edge of the fabric. This may be of particular concern when the prosthesis has a curved configuration as shown. In one embodiment, the apex 40 of the apertures 38 may be spaced inwardly approximately 0,50 -0,76 mm (.020 to . 030 inches) from the outer peripheral edge 28 of the fabric. Of course, one of skill in the art would readily recognize that any suitable aperture configuration may be employed to provide fluid drainage and/or reduce wrinkle development along the outer margin of the prosthesis. For example, the apertures 38 may be configured as a pattern of holes distributed on the portion of the barrier layer overlying the second side of the fabric. In one embodiment, the apertures may have a diameter of approximately 1mm that may be spaced approximately 5mm apart.

[0024] The repair fabric 22 and barrier layer 24 may be configured to have any suitable shape that is conducive to facilitating the repair of a particular defect. In the embodiments illustrated in FIGS. 1-6, the prosthesis 20 has a generally elliptical or oval shape. Examples of other shapes include, but are not limited to, circular, square and rectangular shapes.

[0025] In one embodiment, the repair fabric 22 is formed of a sheet of knitted polypropylene monofilament mesh fabric such as BARD MESH available from C.R. Bard, Inc. When implanted, the polypropylene mesh promotes rapid tissue ingrowth into and around the mesh structure. Alternatively, other surgical materials which are suitable for tissue reinforcement and defect closure may be utilized including PROLENE, SOFT TISSUE PATCH (microporous ePTFE), SURGIPRO, TRELEX, ATRIUM and MERSELENE. Absorbable materials, including polyglactin (VICRYL) and polyglycolic acid (DEXON), may be suitable for applications involving temporary repair of tissue or wall defects. It also is contemplated that the mesh fabric may be formed from multifilament yarns and that any suitable method, such as knitting, weaving, braiding, molding and the like, may be employed to form the prosthetic mesh material.

[0026] In one embodiment, the barrier layer 24 is formed from a sheet of expanded polytetrafluoroethylene (cPTFE) having a pore size (submicronal) that discourages tissue ingrowth and adhesion. Examples of suitable material include FLUORO-TEX Pericardial and Peritoneum Surgical Membrane and FLUORO-TEX Dura Substitute available from C.R Bard and PRECLUDE Pericardial Membrane, PRECLUDE Peritoneal Membrane and PRECLUDE Dura Substitute membrane available from W.L. Gore & Associates, Inc. A representative and non-limiting sampling of other suitable nonporous materials includes silicone elastomer, such as SILASTIC Rx Medical Grade Sheeting (Platinum Cured) distributed by Dow Corning Corporation, TEFLON mesh, and microporous polypropylene sheeting (CELGARD) and film. Autogenous, heterogenous and xenogeneic tissue also are contemplated including, for example, pericardium and small intestine submucosa. Absorbable materials, such as SEPRAFILM available from Genzyme Corporation and oxidized, regenerated cellulose (Intercede (TC7)) may be employed for some applications. It is to be appreciated that any suitable adhesion resistant materials may be used as would be apparent to one of skill in the art.

[0027] In the illustrative embodiments described above, the repair fabric 22 and the barrier layer 24 are integrally connected with one or more connecting stitches 42. As shown in FIGS. 1 and 4, multiple series of stitches 42 (including hem stitches 34, 36) may be formed in a concentric pattern that follows the shape of the prosthesis. Stitching may allow total tissue infiltration to the fabric while providing a strong connection between the fabric and the barrier layer. The concentric pattern also maintains composite integrity by preventing the barrier 24 and underlying fabric 22 from separating should the prosthesis be trimmed by the surgeon to match a particular size and shape of the repair site. Any suitable pattern, however, may be employed so as to minimize separation of the fabric and the barrier layer.

[0028] In one embodiment, the stitches 42 (including hem stitches 34, 36) are formed with a polytetrafluoroethylene (PTFE) monofilament. PTFE stitches may provide a softer, more flexible prosthesis that is easier to manipulate as compared to a prosthesis using other stitch materials, such as polypropylene monofilament. PTFE monofilament also facilitates the manufacturing process due to the low friction characteristics of the material. Additionally, PTFE stitches may tend to be more adhesion resistant than other materials. Nevertheless, it should be understood that any suitable material, such as polypropylene monofilament, may be employed for the stitches.

[0029] The barrier layer 24 may be stitched to the repair fabric 22 by positioning the barrier material on the fabric to face the sewing needle so that the locking portion of each stitch is formed on the fabric side of the composite rather than on the barrier side to reduce the incidence of localized adhesions with tissue and organs.

The stitches may be formed using a #10 ball-tipped needle to reduce the potential incidence of tissue ingrowth through the stitch holes. The sheets of fabric and barrier material may be held by a frame during the sewing procedure on a computer controlled table that has been programmed with the desired stitch pattern.

[0030] Any other suitable fastening technique and material may be employed to attach the barrier layer 24 to the repair fabric 22. For example, the barrier layer 24 may be bonded to the fabric 22 using an adhesive dispensed in a desired pattern, such as a spiral pattern, a serpentine pattern or a grid-like pattern of dots or beads, that maintains a sufficient quantity of open or non-impregnated interstices for tissue infiltration. Alternatively, the barrier layer 24 may be laminated or heat fused to the fabric 22 by a combination of heat and pressure. This lamination technique may be enhanced by a second layer of fabric such as is described in U.S. Patent No. 6,120,539 which is also assigned to C.R. Bard, Inc., the assignee of the present application. The barrier may also be insert molded to the fabric using any suitable molding process.

[0031] It may be desirable to reinforce the outer margin of the prosthesis 20, particularly when the prosthesis may be secured using fasteners, such as sutures, staples and the like, along its outer margin. In one illustrative embodiment, a stitch line 42 (FIG. 3) and 36 (FIG. 6) is provided along the circumference of the prosthesis slightly inward of the peripheral barrier 26 to form a bite region away from the outer peripheral edge 28 of the fabric that is configured to receive a fastener for securing the prosthesis along its circumference. In this regard, a fastener, such as a suture, may be attached to the prosthesis inward of the stitch line 42 so that the stitch line may resist tension placed on the suture. In one embodiment, the stitch line may be located approximately 3mm inward from the outer peripheral edge 28 to form a bite region having a width of approximately 4mm. Of course, any suitable reinforcement configuration apparent to one of skill may be employed along the outer margin of the prosthesis.

[0032] In an exemplary embodiment, the composite prosthesis 20 includes an approximately 0.68 mm (.027 inch) thick sheet 22 of BARD MESH knitted from polypropylene monofilament with a diameter of approximately 0.006 inches. An approximately 0,015 - 0,020 mm (.006 to .008 inch) thick sheet 24 of ePTFE is attached to the mesh using approximately 3mm to 4mm long stitches 42 formed of a 0,020 - 0,030 mm (0.008 inch to 0.012 inch) diameter PTFE monofilament. The prosthesis 20 has a generally elliptical shape that may be configured to have any desired size. The peripheral barrier 26 has a width of approximately 2,54 mm (0.10 inches) with a tapered shape having a thickness of approximately 0,127 mm (.005 inches) at its tip. It should be understood, however, that these dimensions are merely exemplary and that any suitable sizes and shapes may be employed for the prosthesis.

[0033] In the exemplary embodiment, the peripheral barrier 26 is formed by melting a ring of polypropylene mesh fabric 22 to the ePTFE barrier layer 24 in a generally elliptical shape that approximates the desired configuration of the prosthesis. This may be accomplished by overlying oversized sheets of the mesh fabric and ePTFE material in a fixture and heat sealing the layers using a heated die configured with the desired shape of the prosthesis. The melted ring may be formed by applying heat to the fabric at a temperature range of approximately 160°C - 204,4°C (320° F to 400° F) for a period of approximately 3 to 5 seconds. Once fused, the fabric and barrier layer are stitched, as described above, and subsequently die cut flush along a portion of the ring to complete the prosthesis with a peripheral barrier.

[0034] Other illustrative embodiments for isolating the outer peripheral edge of the fabric are shown in FIGS. 8-10.

[0035] In FIG. 8, the interstices or openings along the outer margin 50 may be impregnated or otherwise occluded with a biocompatible material, such as silicone, polyethylene, polypropylene, urethane and the like, so as to inhibit tissue ingrowth that could lead to postoperative adhesions.

[0036] In FIG. 9, a body 52 of adhesion resistant material, such as a silicone, polyethylene, polypropylene, ePTFE, urethane and the like, may be deployed about the outer peripheral edge 28 of the repair fabric. Absorbable materials, such as SEPRAFILM available from Genzyme Corporation and oxidized, regenerated cellulose (Intercede (TC7)) may be employed for some applications. It is to be appreciated that any suitable.adhesion resistant materials may be used as would be apparent to one of skill in the art.

[0037] In FIG. 10, a second barrier layer 54 may be placed along the outer margin of the second side of the repair fabric with the outer margin 56 of the fabric being melted and sealed between the first and second barrier layers.

[0038] It is to be understood, however, that the above embodiments are exemplary and any suitable peripheral barrier configuration may be implemented to isolate the outer peripheral edge of the fabric from developing adhesions to adjacent tissue and organs.

[0039] The present invention provides a prosthetic repair fabric having certain of the following advantages. The composite prosthesis combines the low adhesion incidence of a physical barrier over portions the repair fabric, including its outer peripheral edge, with desirable tissue ingrowth to the host tissue. The composite may be anchored in place by tissue ingrowth into the fabric interstices and/or may be sutured, stapled and the like to tissue.

[0040] It should be understood that the foregoing description of the invention is intended merely to be illustrative thereof and that other embodiments, modifications, and equivalents of the invention are within the scope of the invention recited in the claims appended

hereto.

Claims

1. An implantable prosthesis (20) for repairing a tissue or muscle wall defect, the implantable prosthesis comprising:

   a layer of repair fabric (22) that is susceptible to the formation of adhesions with tissue and organs, the layer of repair fabric including a first surface (30) and an outer peripheral edge (28);
   a barrier layer (24) that inhibits the formation of adhesions with tissue and organs, the barrier layer being configured to inhibit the formation of adhesions between at least a portion of the first surface and adjacent tissue and organs; and **characterised by**
   a peripheral barrier (26) that inhibits the formation of adhesions with tissue and organs, the peripheral barrier extending about at least a portion of the outer peripheral edge of the layer of repair fabric to inhibit the formation of adhesions between the portion of the outer peripheral edge of the layer of repair fabric and adjacent tissue and organs.

2. The implantable prosthesis according to claim 1, wherein the layer of repair fabric includes a plurality of interstices that are constructed and arranged to allow tissue ingrowth thereto.

3. The implantable prosthesis according to any of the preceding claims, wherein the peripheral barrier includes an outer margin of the layer of repair fabric that has been altered to inhibit the formation of adhesions thereto.

4. The implantable prosthesis according to claim 3, wherein a portion of the outer margin has been melted and resolidified to render the portion of the outer peripheral edge of the layer of repair fabric substantially impervious to tissue ingrowth.

5. The implantable prosthesis according to any of the preceding claims, wherein the peripheral barrier has a tapered shape.

6. The implantable prosthesis according to any of the preceding claims, wherein the peripheral barrier has a thickness that decreases in an outward direction away from the outer peripheral edge of the layer of repair fabric.

7. The implantable prosthesis according to any of the preceding claims, wherein the layer of repair fabric includes a second surface (32), the peripheral barrier tapering from the second surface of the layer of repair fabric at the outer peripheral edge thereof toward the barrier layer.

8. The implantable prosthesis according to any of claims 1 to 2, wherein the peripheral barrier includes a section of the barrier layer that extends about the portion of the outer peripheral edge.

9. The implantable prosthesis according to claim 8, wherein the layer of repair fabric includes a second surface opposite the first surface, the section of the barrier layer extending over a portion of the second surface of the layer of repair fabric adjacent the outer peripheral edge.

10. The implantable prosthesis according to claim 9, wherein the section of the barrier layer extending over the portion of the second surface includes a plurality of fluid drainage apertures (38) adjacent the outer peripheral edge.

11. The implantable prosthesis according to claim 10, wherein the plurality of fluid drainage apertures include a plurality of slits extending inwardly away from the outer peripheral edge.

12. The implantable prosthesis according to claim 11, wherein each of the plurality of slits has a generally V-shape.

13. The implantable prosthesis according to any of claims 10 to 12, wherein the plurality of fluid drainage apertures are spaced inwardly away from the outer peripheral edge.

14. The implantable prosthesis according to any of the preceding claims, wherein the layer of repair fabric includes an outer perimeter, the peripheral barrier extending along the entire outer perimeter.

15. The implantable prosthesis according to any of the preceding claims, wherein the layer of repair fabric and the barrier layer are connected by at least one series of stitches (34, 36).

16. The implantable prosthesis according to claim 15, wherein the series of stitches are disposed slightly inward of the outer peripheral edge.

17. The implantable prosthesis according to any of claims 15 to 16, wherein the series of stitches are formed from an adhesion resistant material.

18. The implantable prosthesis according to claim 17, wherein the adhesion resistant material includes PTFE.

19. The implantable prosthesis according to any of claims 15 to 18, wherein the at least one series of stitches includes a plurality of series of stitches.

20. The implantable prosthesis according to claim 19, wherein the layer of repair fabric includes a predetermined outer perimeter shape, the plurality of series of stitches including at least one series of stitches that follows the predetermined outer perimeter shape.

21. The implantable prosthesis according to any of claims 19 to 20, wherein the plurality of series of stitches are arranged in a concentric pattern.

22. The implantable prosthesis according to any of claims 1 to 2, wherein the layer of repair fabric includes an inner body and an outer margin extending from the inner body, each of the inner body and the outer peripheral edge having a thickness, the thickness of the outer peripheral edge being less than the thickness of the inner body.

23. The implantable prosthesis according to any of claims 3, 4 or 22, wherein the outer margin has a non-uniform thickness.

24. The implantable prosthesis according to any of claims 3, 4 or 22 to 23, wherein the outer margin has a tapered shape.

25. The implantable prosthesis according to any of claims 3, 4 or 22 to 24, wherein the layer of repair fabric includes an outer perimeter, the outer margin (50) having been melted and resolidified along the entire outer perimeter.

26. The implantable prosthesis according to any of claims 3, 4 or 22-25, wherein the outer margin is reinforced to form a bite region for securing the prosthesis along the outer margin.

27. The implantable prosthesis according to claim 26, further comprising a plurality of stitches disposed inward of the outer peripheral edge to form the bite region.

28. The implantable prosthesis according to claim 27, wherein the plurality of stitches join the barrier layer to the layer of repair fabric.

29. The implantable prosthesis according to any of the preceding claims, wherein the barrier layer covers the entire first surface of the layer of repair fabric.

30. The implantable prosthesis according to any of the preceding claims, wherein the layer of repair fabric includes a polypropylene mesh.

31. The implantable prosthesis according to any of the preceding claims, wherein the barrier layer includes ePTFE.

Patentansprüche

1. Implantierbare Prothese (20) zur Reparatur eines Gewebe- oder Muskelwanddefekts, wobei die implantierbare Prothese umfasst:

   eine Lage Reparaturstoff (22), die zur Bildung von Adhäsionen mit Gewebe und Organen neigt, wobei die Lage Reparaturstoff eine erste Oberfläche (30) und einen äußeren Umfangsrand (28) aufweist;
   eine Sperrschichtlage (24), die die Bildung von Adhäsionen mit Gewebe und Organen verhindert, wobei die Sperrschichtlage so gestaltet ist, dass sie die Bildung von Adhäsionen zwischen zumindest einem Teil der ersten Oberfläche und angrenzendem Gewebe und angrenzenden Organen verhindert; und **gekennzeichnet durch**:

      eine umfängliche Sperrschicht (26), die die Bildung von Adhäsionen mit Gewebe und Organen verhindert, wobei sich die umfängliche Sperrschicht über mindestens einen Teil der äußeren Umfangskante der Lage Reparaturstoff erstreckt, um die Bildung von Adhäsionen zwischen dem Teil des äußeren Umfangsrandes der Lage Reparaturstoff und angrenzendem Gewebe und angrenzenden Organen zu verhindern.

2. Implantierbare Prothese nach Anspruch 1, wobei die Lage Reparaturstoff mehrere Lücken enthält, die so konstruiert und angeordnet sind, dass ein Einwachsen von Gewebe in diese möglich ist.

3. Implantierbare Prothese nach einem der vorangehenden Ansprüche, wobei die umfängliche Sperrschicht einen äußeren Rand der Lage des Reparaturstoffes enthält, der verändert wurde, um die Bildung von Adhäsionen an diesem zu verhindern.

4. Implantierbare Prothese nach Anspruch 3, wobei ein Teil des äußeren Randes geschmolzen und wieder verfestigt wird, um den Teil des äußeren Umfangsrandes der Lage Reparaturstoff im Wesentlichen für das Einwachsen von Gewebe undurchdringbar zu machen.

5. Implantierbare Prothese nach einem der vorangehenden Ansprüche, wobei die umfängliche Sperrschicht eine konisch zulaufende Form hat.

6. Implantierbare Prothese nach einem der vorangehenden Ansprüche, wobei die umfängliche Sperrschicht eine Dicke aufweist, die in Auswärtsrichtung weg vom äußeren Umfangsrand der Lage Reparaturstoff abnimmt.

7. Implantierbare Prothese nach einem der vorangehenden Ansprüche, wobei der Reparaturstoff eine zweite Oberfläche (32) enthält, wobei die umfängliche Sperrschicht von der zweiten Oberfläche der Lage Reparaturstoff an deren äußerer Umfangskante zu der Sperrschichtlage hin konisch zuläuft.

8. Implantierbare Prothese nach einem der Ansprüche 1 bis 2, wobei die umfängliche Sperrschicht einen Abschnitt der Sperrschichtlage enthält, der sich um den Teil des äußeren Umfangsrandes erstreckt.

9. Implantierbare Prothese nach Anspruch 8, wobei die Lage Reparaturstoff eine zweite Oberfläche gegenüber der ersten Oberfläche enthält, wobei sich der Abschnitt der Sperrschichtlage über einen Teil der zweiten Oberfläche der Lage Reparaturstoff neben dem äußeren Umfangsrand erstreckt.

10. Implantierbare Prothese nach Anspruch 9, wobei der Abschnitt der Sperrschicht, der sich über einen Teil der zweiten Oberfläche erstreckt, mehrere Flüssigkeitsableitungsöffnungen (38) neben dem äußeren Umfangsrand enthält.

11. Implantierbare Prothese nach Anspruch 10, wobei die mehreren Flüssigkeitsableitungsöffnungen mehrere Schlitze enthalten, die sich von dem äußeren Umfangsrand weg nach innen erstrecken.

12. Implantierbare Prothese nach Anspruch 11, wobei jeder der mehreren Schlitze im wesentlichen V-förmig ist.

13. Implantierbare Prothese nach einem der Ansprüche 10 bis 12, wobei die mehreren Flüssigkeitsableitungsöffnungen vom äußeren Umfangsrand nach innen beabstandet sind.

14. Implantierbare Prothese nach einem der vorangehenden Ansprüche, wobei die Lage Reparaturstoff einen äußeren Umfang aufweist und sich die umfängliche Sperrschicht entlang dem gesamten äußeren Umfang erstreckt.

15. Implantierbare Prothese nach einem der vorangehenden Ansprüche, wobei die Lage Reparaturstoff und die Sperrschichtlage durch mindestens eine Reihe von Nähten (34, 36) miteinander verbunden sind.

16. Implantierbare Prothese nach Anspruch 15, wobei die Reihe von Nähten etwas innerhalb der äußeren Umfangskante angeordnet ist.

17. Implantierbare Prothese nach einem der Ansprüche 15 bis 16, wobei die Reihe von Nähten aus einem adhäsionsbeständigen Material gebildet ist.

18. Implantierbar Prothese nach Anspruch 17, wobei das adhäsionsbeständige Material PTFE ist.

19. Implantierbare Prothese nach einem der Ansprüche 15 bis 18, wobei die mindestens eine Reihe von Nähten mehrere Reihen von Nähten enthält.

20. Implantierbare Prothese nach Anspruch 19, wobei die Lage Reparaturstoff eine vorbestimmte äußere Umfangsform aufweist, die mehreren Reihen von Nähten mindestens eine Reihe von Nähten enthalten, die der vorbestimmten äußeren Umfangsform folgt.

21. Implantierbare Prothese nach einem der Ansprüche 19 bis 20, wobei die mehreren Reihen von Nähten in einem konzentrischen Muster angeordnet sind.

22. Implantierbare Prothese nach einem der Ansprüche 1 bis 2, wobei die Lage Reparaturstoff einen inneren Körper und einen äußeren Rand enthält, der sich von dem inneren Körper erstreckt, wobei sowohl der innere Körper als auch der äußere Umfangsrand eine Dicke aufweisen, die geringer ist als die Dicke des inneren Körpers.

23. Implantierbare Prothese nach einem der Ansprüche 3, 4 oder 22, wobei der äußere Rand eine ungleichförmige Dicke hat.

24. Implantierbare Prothese nach einem der Ansprüche 3, 4 oder 22 bis 23, wobei der äußere Rand eine konisch zulaufende Form hat.

25. Implantierbare Prothese nach einem der Ansprüche 3, 4 oder 22 bis 24, wobei die Lage Reparaturstoff einen äußeren Umfang aufweist und der äußere Rand (50) entlang seinem gesamten äußeren Umfang geschmolzen und wieder verfestigt wurde.

26. Implantierbare Prothese nach einem der Ansprüche 3, 4 oder 22 bis 25, wobei der äußere Rand verstärkt ist, um einen Eingriffsbereich zur Befestigung der Prothese entlang dem äußeren Rand zu bilden.

27. Implantierbare Prothese nach Anspruch 26, des Weiteren umfassend mehrere Nähte, die innerhalb der äußeren Umfangskante zur Bildung des Eingriffsbereichs angeordnet sind.

28. Implantierbare Prothese nach Anspruch 27, wobei die mehreren Nähte die Sperrschichtlage mit der Lage Reparaturstoff verbinden.

29. Implantierbare Prothese nach einem der vorangehenden Ansprüche, wobei die Sperrschichtlage die gesamte erste Oberfläche der Lage Reparaturstoff bedeckt.

30. Implantierbare Prothese nach einem der vorangehenden Ansprüche, wobei die Lage Reparaturstoff ein Polypropylennetz enthält.

31. Implantierbare Prothese nach einem der vorangehenden Ansprüche, wobei die Sperrschichtlage ePTFE enthält.

Revendications

1. Une prothèse implantable (20) destinée à la réparation d'un défaut de la paroi tissulaire ou musculaire, cette prothèse implantable comprenant :

   - une couche d'un tissu réparateur (22) susceptible de créer des adhérences avec le tissu et les organes, cette couche de tissu réparateur comportant une première surface (30) et un bord périphérique extérieur (28),
   - une couche barrière (24) qui inhibe la formation d'adhérences avec le tissu et les organes, cette couche barrière ayant une configuration telle qu'elle inhibe la formation d'adhérences entre au moins une portion de la première surface et le tissu et les organes adjacents,

   caractérisée par une barrière périphérique (26) qui inhibe la formation d'adhérences avec le tissu et les organes, cette barrière périphérique s'étendant sur au moins une portion du bord périphérique extérieur de la couche de tissu réparateur en vue d'inhiber la formation d'adhérences entre la portion du bord périphérique extérieur de la couche de tissu réparateur et le tissu et les organes adjacents.

2. La prothèse implantable selon la Revendication 1, dans laquelle la couche de tissu réparateur comporte une pluralité d'interstices créés et répartis de manière à y permettre la croissance de tissu.

3. La prothèse implantable selon l'une ou l'autre des Revendications 1 ou 2, dans laquelle la barrière périphérique inclut une marge extérieure de la couche de tissu réparateur qui a été modifiée de manière à inhiber la formation sur elle d'adhérences.

4. La prothèse implantable selon la Revendication 3, dans laquelle une portion de la marge extérieure a été fondue et re-solidifiée de manière à rendre la portion du bord périphérique extérieur de la couche de tissu réparateur imperméable à la croissance de tissu à l'intérieur.

5. La prothèse implantable selon l'une quelconque des Revendications précédentes, dans laquelle la barrière périphérique a une forme amincie.

6. La prothèse implantable selon l'une quelconque des Revendications précédentes, dans laquelle la barrière périphérique a une épaisseur qui diminue vers l'extérieur, dans la direction s'éloignant du bord périphérique extérieur de la couche de tissu réparateur.

7. La prothèse implantable selon l'une quelconque des revendications précédentes, dans laquelle la couche de tissu réparateur comporte une seconde surface (32), la barrière périphérique s'amincissant depuis la seconde surface de la couche de tissu réparateur à l'emplacement de son bord périphérique extérieur vers la couche barrière.

8. La prothèse implantable selon l'une des Revendications 1 ou 2, dans laquelle la barrière périphérique inclut une section de la couche barrière qui s'étend sur la portion du bord périphérique extérieur.

9. La prothèse implantable selon la Revendication 8, dans laquelle la couche de tissu réparateur présente une seconde surface opposée à la première surface, la section de la couche barrière s'étendant sur la portion de la seconde surface de la couche de tissu réparateur adjacente au bord périphérique extérieur.

10. La prothèse implantable selon la Revendication 9, dans laquelle la section de la couche barrière s'étendant sur la portion de la seconde surface comporte une pluralité d'ouvertures d'écoulement de fluide (38) adjacentes au bord périphérique extérieur.

11. La prothèse implantable selon la Revendication 10, dans laquelle la pluralité d'ouvertures d'écoulement de fluide consiste en une pluralité de fentes s'étendant vers l'intérieur en s'éloignant du bord périphérique extérieur.

12. La prothèse implantable selon la Revendication 11, dans laquelle chacune des fentes a une forme générale en V.

13. La prothèse implantable selon l'une quelconque des Revendications 10 à 12, dans laquelle la pluralité d'ouvertures d'écoulement de fluide sont espa-

cées vers l'intérieur en s'éloignant du bord périphérique.

14. La prothèse implantable selon l'une quelconque des Revendications précédentes, dans laquelle la couche de tissu réparateur est délimitée par un périmètre extérieur, la barrière périphérique s'étendant le long de la totalité du périmètre extérieur.

15. La prothèse implantable selon l'une quelconque des Revendications précédentes, dans laquelle la couche de tissu réparateur et la couche barrière sont réunies par au moins une série de piqûres (34, 36).

16. La prothèse implantable selon la Revendication 15, dans laquelle la série de piqûres est disposée légèrement vers l'intérieur par rapport au bord périphérique extérieur.

17. La prothèse implantable selon l'une des Revendications 15 ou 16, dans laquelle la série de piqûres est réalisée au moyen d'un matériau résistant à l'adhérence.

18. La prothèse implantable selon la Revendication 17, dans laquelle le matériau résistant à l'adhérence est du PTFE.

19. La prothèse implantable selon l'une quelconque des Revendications 15 à 18, dans laquelle au moins une série de piqûres comprend une pluralité de séries de piqûres.

20. La prothèse implantable selon la Revendication 19, dans laquelle la couche de tissu réparateur présente un périmètre extérieur de forme prédéterminée, la pluralité des séries de piqûres comprenant au moins une série de piqûres qui suit la forme prédéterminée du périmètre extérieur.

21. La prothèse implantable selon l'une ou l'autre des Revendications 19 ou 20, dans laquelle la pluralité de séries de piqûres sont réparties suivant un motif concentrique.

22. La prothèse implantable selon l'une ou l'autre des revendications 1 ou 2, dans laquelle la couche de tissu réparateur comporte un corps intérieur et une marge extérieure partant du corps intérieur, le corps intérieur et le bord périphérique extérieur ayant chacun une épaisseur, l'épaisseur du bord périphérique extérieur étant inférieure à l'épaisseur du corps intérieur.

23. La prothèse implantable selon l'une quelconque des Revendications 3, 4 ou 22, dans laquelle la marge extérieure a une épaisseur non-uniforme.

24. La prothèse implantable selon l'une quelconque des Revendications 3, 4, 22 ou 23, dans laquelle la marge extérieure a une forme amincie.

25. La prothèse implantable selon l'une quelconque des Revendications 3, 4, 22 ou 24, dans laquelle la couche de tissu réparateur présente un périmètre extérieur, la marge extérieure (50) ayant été fondue et re-solidifiée le long de la totalité du périmètre extérieur.

26. La prothèse implantable selon l'une quelconque des Revendications 3, 4 ou 22-25, dans laquelle la marge extérieure est renforcée de manière à former une région de prise pour la fixation de la prothèse le long de la marge extérieure.

27. La prothèse implantable selon la Revendication 26, comprenant au surplus une pluralité de piqûres disposées vers l'intérieur du bord périphérique extérieur, de manière à former une région de prise.

28. La prothèse implantable selon la Revendication 27, dans laquelle la pluralité de piqûres réunissent la couche barrière à la couche de tissu réparateur

29. La prothèse implantable selon l'une quelconque des Revendications précédentes, dans laquelle la couche barrière recouvre la totalité de la première surface de la couche de tissu réparateur

30. La prothèse implantable selon l'une quelconque des Revendications précédentes, dans laquelle la couche de tissu réparateur consiste en un maillage de polypropylène.

31. La prothèse implantable selon l'une quelconque des revendications précédentes, dans laquelle la couche barrière contient du PTFE.

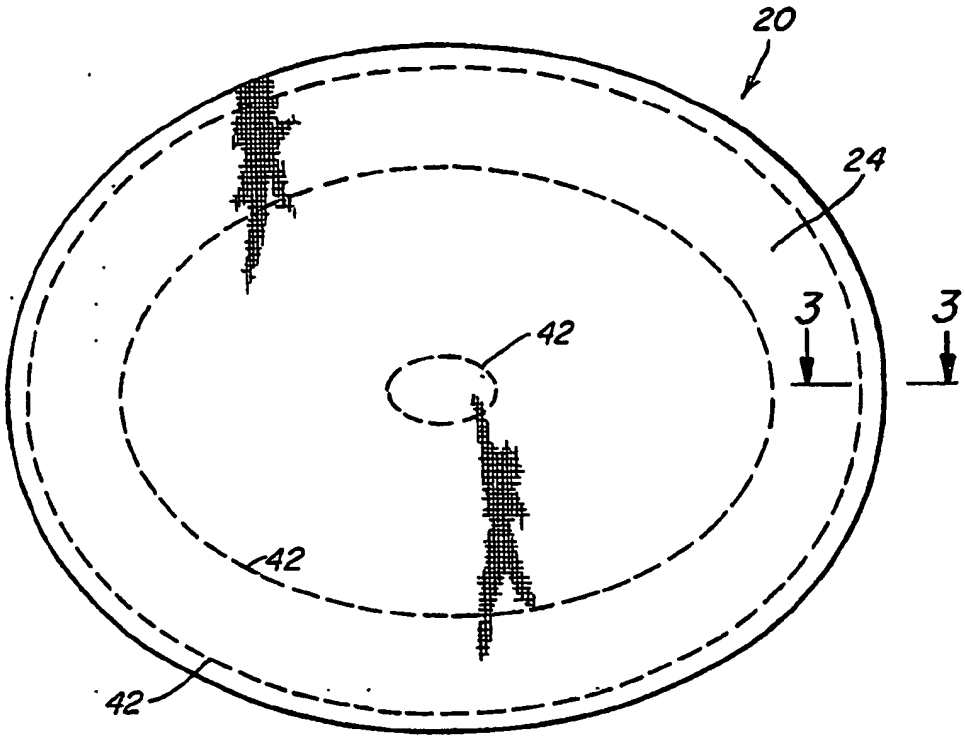

Fig. 1

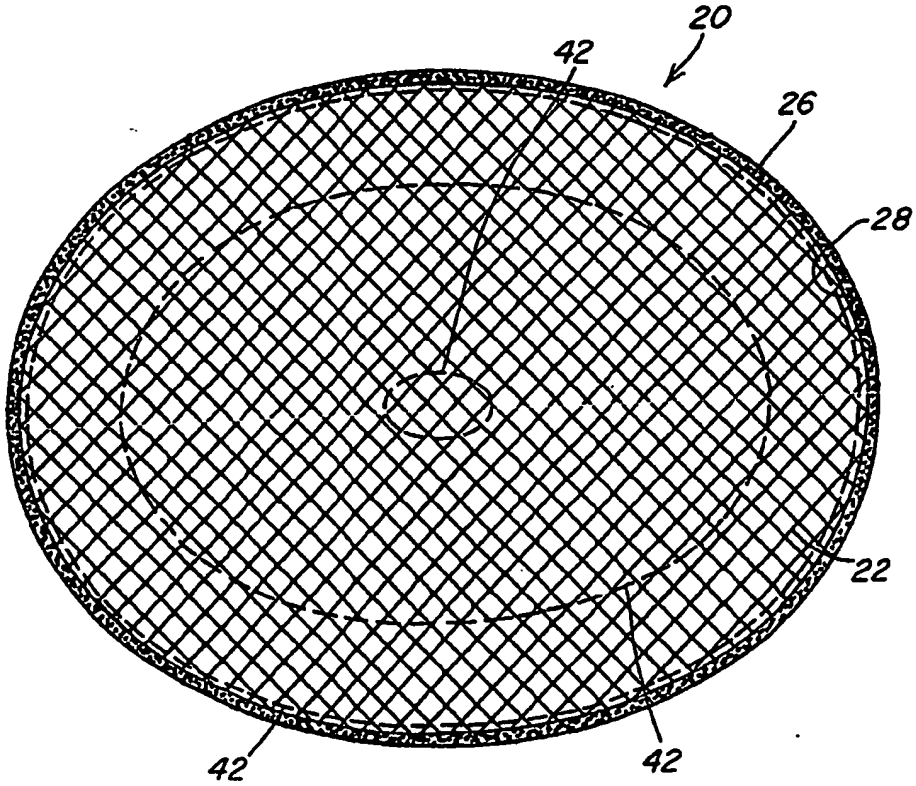

Fig. 2

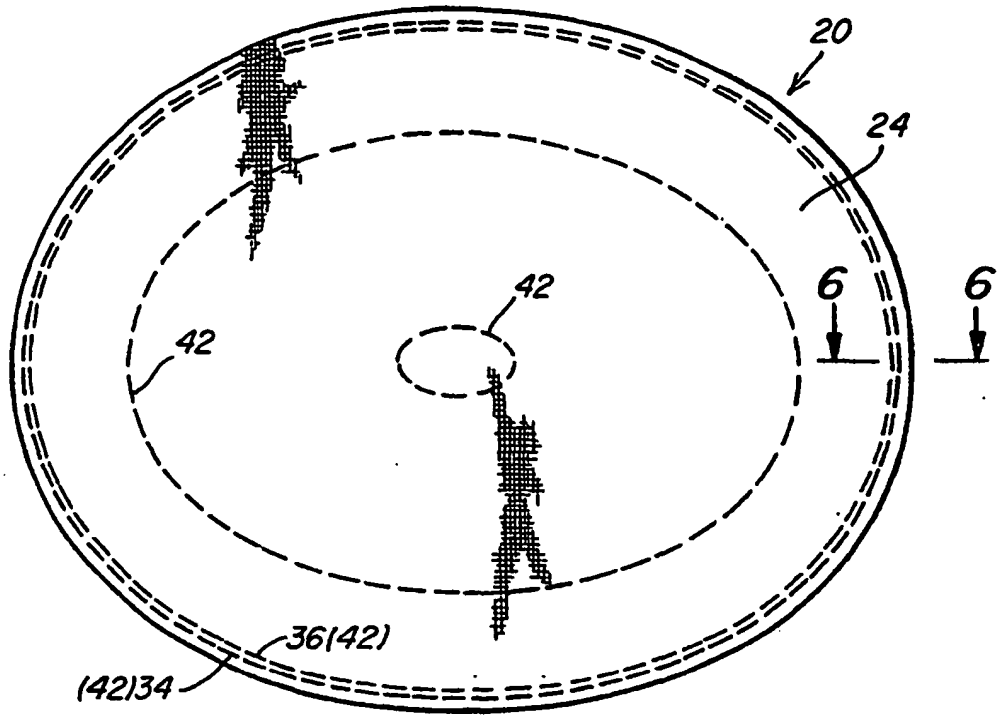

Fig. 4

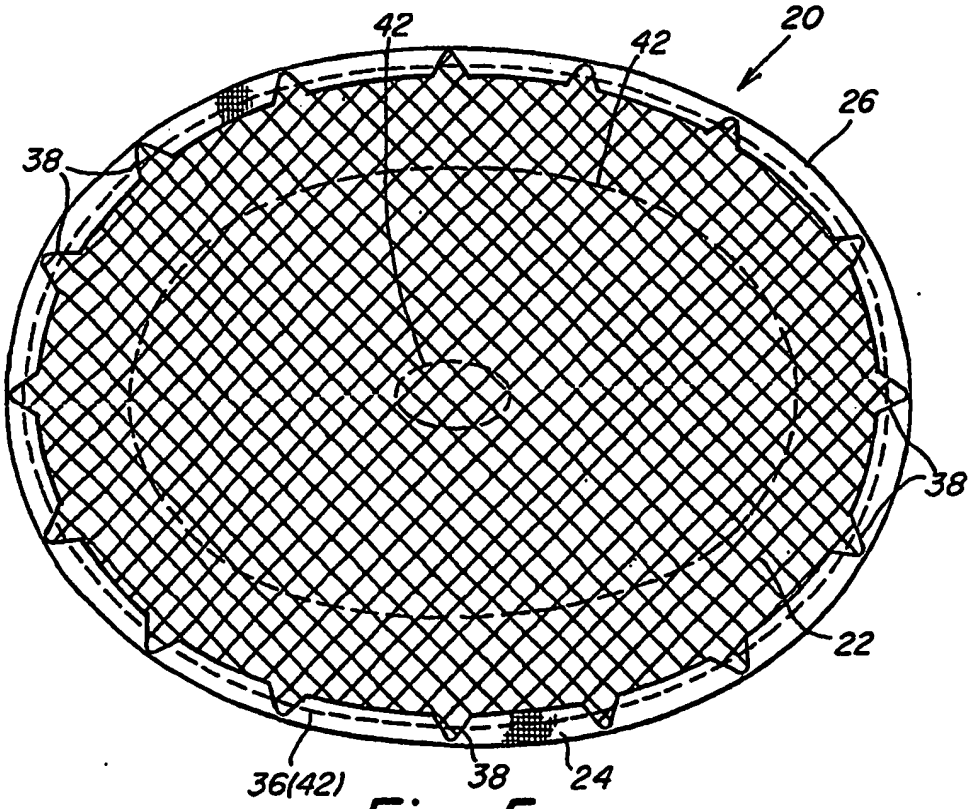

Fig. 5

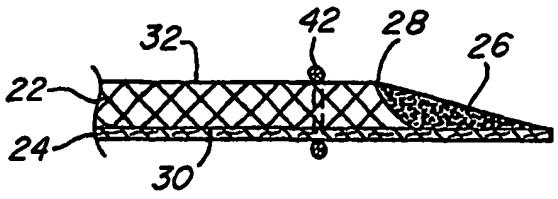

Fig. 3

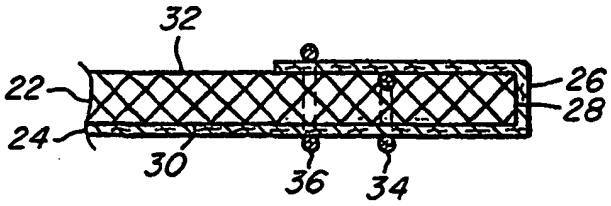

Fig. 6

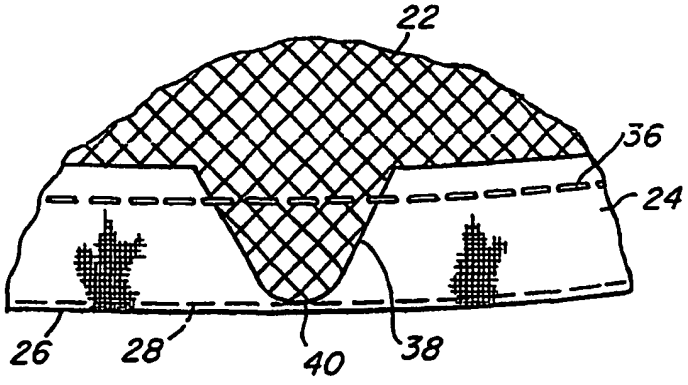

Fig. 7

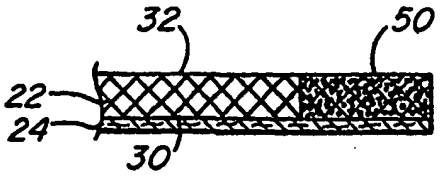

Fig. 8

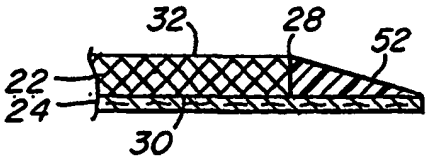

Fig. 9

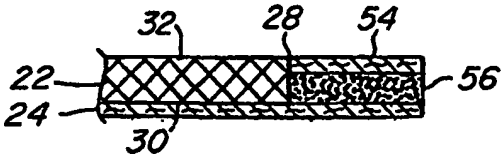

Fig. 10